

Re-Engineering Engineering Education

BIOMATERIALS FORUM



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BIOMATERIALS FORUM



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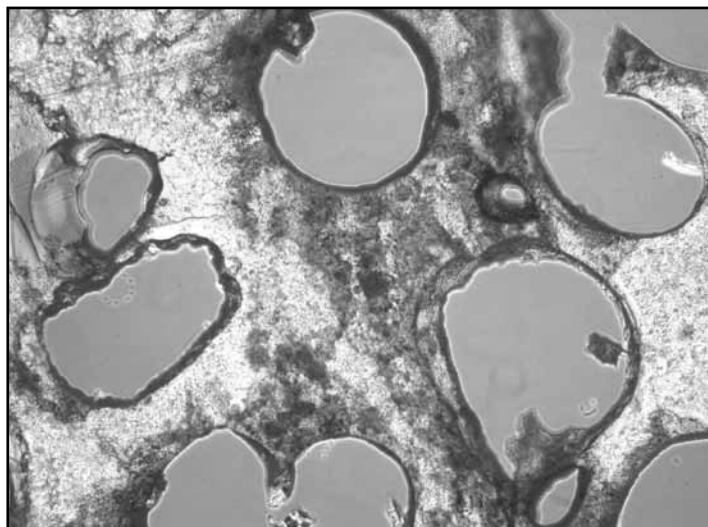
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On the cover: Dahl's staining of a poly(lactide)/poly(caprolactone)/hydroxyapatite porous scaffold following 28 days of culture in a perfusion bioreactor with human mesenchymal stem cells. Red/orange indicates calcium presence, photograph taken at 100X original total magnification. Photograph courtesy of Dr. Scott Maxson of the Clemson University Department of Bioengineering and the Clemson University Institute for Biological Interfaces of Engineering.



I start my column with this seemingly innocuous question—who is a biomaterialist? Those of you who raised your hands (which I would expect to be most of the *Forum* readers) have just volunteered to help wrestle with the tough questions of how a biomaterialist should be trained and if they should be licensed. Our field exists at the

confluence of engineering, physics, medicine, biology, and ethics; most biomaterialists are raised in the estuaries of these individual fields before entering the open waters of biomaterials practice. Thus, the identification of a core set of training goals that can later be evaluated through a licensing or certification process appears daunting. Does this mean that we should not try? I would suggest that we must address these issues to promote the health and relevance of SFB.

Maybe we should first try to identify, from amongst our colleagues, those who are good biomaterialist role models and then analyze their career paths. The composition of SFB is a mix of technical backgrounds—i.e. our ranks include engineers, life scientists, physical scientists, and others. How did each grow as a student to become a successful biomaterialist? Was it really simply their ability to complete a fluid mechanics course or a course in cell biology? In my home discipline, a biomaterials engineer learns a broad spectrum of technical skills as basic training but needs to be able to see the big picture and put their finely focused area in the context of that big picture in order to truly be called a biomaterialist. To do so, they must have perspective of the big picture, and to gain that perspective, they must be surrounded by biomaterialists who are experts in a wide range of disciplines who analyze the biomaterials questions from very different angles. To me, the foundational piece that makes a biomaterialist is that which sculpts us and equips us with the tools to think more broadly, but with highly ordered vision.

So how, indeed, do we provide a common educational framework designed to cultivate a biomaterialist? Most biomedical engineering programs have attempted to answer the training question in general by providing a broad-based training. I am sure those of us in academic departments in biomaterials engineering related fields have had similar conversations as we consider the future of the graduate programs in our department—should we have tracks that are specific to students with life science backgrounds versus students with engineering backgrounds? And should the terminal degree be the same regardless of track? The recent Society For Biomaterials meeting, specifically the education panel discussion, raised the issue of a standardized undergraduate biomaterials curriculum—do we need to have a minimum common base of knowledge in order to be considered a “biomaterialist?” This is a very important discussion, with the goal of ensuring a common biomaterials language but allowing enough freedom beyond the basics to inspire and to facilitate creative latitude in teaching. Such a curriculum would benefit

from clinical and industry input and perspective, not just at a senior capstone design point, but woven throughout. That is, at the panel discussion it was suggested that perhaps we need a professional standard for instruction. Regardless of whether we consider undergraduate or graduate training, the issue is common—how will we develop the best prepared biomaterialists who will tackle the big issues of our field? I truly believe we’ve reached a mature point in the field, where we can begin to more sensibly answer this question. I’ve often heard the excuse, “Well, I’m just interested in biomaterials research. I’m not interested in wasting time on committees, discussing mundane issues ad nauseam, etc.” I would argue that the enjoyable research environment does not magically occur; in fact, it is the product of people with in-depth knowledge of the research environment and a wide array of technical backgrounds who step up and participate in a knowledge-building, management-building process.

Once we consider the training piece, we move to the issue of licensing. Other fields that already have licensure provide the motivation for this formality, including recognition of the profession, quality of practice and commonality of training. The fact that many biomaterialists are called on to serve as expert witnesses or consultants, and that the biomaterials stakes may be even higher than in many disciplines where professional certification already exists, suggests the need for certification/licensure. I wonder where we should begin? Looking at my own background in engineering, perhaps a biomaterialist should be licensed as an engineer? That is, one might suggest there should be a professional engineering (PE) examination to credential biomaterials engineers. It is tempting to agree, but there are several important issues that should be considered. Currently, to be PE certified, one must have an accredited undergraduate engineering degree, which would exclude many highly qualified individuals from biomaterials (or in this case, biomaterials engineering) certification. What about materials scientists, for example? Should they not be considered qualified for “biomaterials engineering certification?” If we look to other, non-engineering disciplines and seek certification through their processes, I suspect we will face similar practical and territorial roadblocks and will need to create our own, biomaterials-relevant certification model.

I think it’s time to turn from animated conversation to action! OK, put your hands down, but remember, you volunteered for the job of helping our Society mature.

Best wishes from Clemson,

Karen J.L. Burg
Hunter Endowed Chair & Professor of Bioengineering
Interim Vice Provost for Research & Innovation
Clemson University



The Society For Biomaterials is an outstanding society because of the commitment of its volunteers. It is important to recognize that the annual meeting and the annual operations of the Society would not be possible without volunteers. I would like to acknowledge their contributions.

This year was challenging for the SFB Board. Needless to say, the economy had an impact on us, but it was because of the efforts of the Board members that we were able to overcome this potential obstacle. I would like to thank Antonios Mikos, Secretary-Treasurer, and Dan Lemyre, SFB Executive Director, for keeping us within budget. I would also like to thank Laura Suggs, Secretary-Treasurer-Elect, and the Finance Committee for all of their hard work in developing a budget for 2010 that will enable us to accomplish our goals while being fiscally responsible. No small task! A special note of appreciation goes to Martine LaBerge for all of her guidance throughout the year. Martine is leaving the Board and Council after 18 continuous years of outstanding service. Thanks also to the other members of the board—Jeremy Gilbert, Jeffrey Hubbell, Michelle Marcolongo and Christopher Siedlecki—for their strong efforts as leaders of this Society.

The SFB Council comprises the Chairs of the standing committees of the Society. Each committee is made up of at least three and as many as 26 SFB members. The committees conduct the work of the Society, and this year was no exception. This was a productive year, notable for the many accomplishments of the committees.

Thank you to each committee member:

Audit Committee: Martine LaBerge, chair; Art Coury, Stuart Goodman

Awards, Ceremonies, and Nominations Committee: Jack Lemons, chair; David Castner, Liisa Kuhn, Robert Latour, Krishnendu Roy

Bylaws Committee: Lisa Friis, Chair; Angela Au, Joel Bumgardner, Timmie Topoleski, Horst von Recum

Devices and Materials Committee: Gabriele Niederauer, Chair; Jeremy Gilbert, Warren Haggard, Kristine Kieswetter, Paul Spencer

Education and Professional Development Committee: David Kohn, Chair; Joel Bumgardner, Alan Litsky, Margaret Phillips, Shane Phillips

Finance Committee: Laura Suggs, Chair; John Fisher, Alan Litsky, Antonios Mikos, Johnna Temenoff

Liaison Committee: Molly Shoichet, Chair; Kristi Anseth, Kevin Healey, William Wagner

Long Range Planning Committee: Jeremy Gilbert, Chair; Guillermo Ameer, Joel Collier, Robert Hastings, Helen Lu, Michele Marcolongo, Kristen Moffat

Meetings Committee: Lynne Jones, Chair; Harold Aberman, Karen Burg, Alastair Clemow, Heather Doty, Phil Messersmith, Antonios Mikos, Buddy Ratner, Nicholas Ziats

Membership Committee: Nicholas Ziats, Chair; Robert Hastings, Helen Lu, Jiro Nagatomi, Christopher Siedlecki

Program Committee: Phil Messersmith, Chair; Karen Burg, Joel Collier, Lara Gamble, Lori Henderson, Lynne Jones, William Murphy, Lawrence Salvati, Christopher Siedlecki, Nicholas Ziats

Publications Committee: Ashutosh Chilkoti, Chair; James Anderson, Karen Burg, Jeremy Gilbert, David Grainger, Syed Hossainy, John Ricci, Thomas Webster

President's Advisory Committee: Jeffrey Hubbell, Chair; Martine LaBerge, Mauli Agrawal, Michael Sefton, James Anderson, Robert Baier, Jonathan Black, Jim Burns, Alastair Clemow, Francis Cooke, Stuart Cooper, Art Coury, Paul Ducheyne, Stuart Goodman, Allan Hoffman, Samuel Hulbert, J. Lawrence Katz, Jack Lemons, Linda Lucas, Anne Meyer, Jack Paar, Russell Parsons, Nicholas Peppas, Buddy Ratner, Frederick Schoen, Myron Spector

Special Interest Group Chair Committee: Christopher Siedlecki, Chair; Carl McMillin, Todd McDevitt, Elizabeth Friis, Peter Edelman, Hyun Joon Kong, Liisa Kuhn, Janson Emmanuel, Thomas Webster, Jinyu Huang, Lakshmi Nair, Carl Simon, Jr., Jeffrey Schwartz, Jan Stegemann

One of the pillars of the Society is its publications group. Thanks to each of the editors for their dedication and for setting such a high standard for our publications. Thank you to the following editors:

JBMR-A: James Anderson; **JBMR-B:** Jeremy Gilbert; **Biomaterials Forum:** Karen Burg; **website:** Thomas Webster; **Textbook:** Buddy Ratner, Allan Hoffman, Frederick Schoen, Jack Lemons; **Book Series:** Nicholas Peppas and Jeffrey Hubbell

A note of appreciation goes out to the SFB members who contribute to the success of our journals including members of the Editorial Boards, the Associate and Assistant Editors, the reviewers and the authors of the articles.

I would like to acknowledge all of the members that enable us to hold such an outstanding annual meeting. These include the organizers and participants in the workshops, tutorials, panel discussions and symposia. Thank you to each member who submitted abstracts and who presented at our meeting.

Regarding the "business" of the Society, two contracts were under negotiation during the past year. Thank you, Anne Meyer, for your focus and expertise during the renegotiation of the contract with Association Headquarters. Thanks also to Jack Ricci for beginning the process with Wiley concerning the contract for the journals.

Continued on Page 5

Hello from Society For Biomaterials headquarters! Your headquarters staff is pleased to report the Annual Meeting in Seattle, April 21-24, had a record turnout of about 1,400 attendees even with volcanic ash creating travel problems for some of our members abroad. The energy generated at this meeting was inspiring, and we hope more members will take an active role in the Society in the months ahead.

Annual Business Meeting

The Society's Annual Business meeting took place April 23, 2010. The results of the spring election were announced, and the following people have been elected as officers for the Board of Directors:

Karen Burg, PhD, Clemson University – President-Elect
Warren Haggard, PhD, University of Memphis – Member-At-Large

New Council

These members will be serving as chairs of committees and, along with the Board, will comprise the 2010-2011 Council: Art Coury, Awards, Ceremonies and Nominations; Joel Bumgardner, Bylaws; Gabriele Niederauer, Devices and Materials; Julie Hasenwinkel, Education and Professional Development; Laura Suggs, Finance; Molly Shoichet, Liaison; Karen Burg, Long-Range Planning; Jeremy Gilbert, Meetings; Bob Hastings, Membership; Lynne Jones, President's Advisory; Nick Ziats, Program; Ashutosh Chilkoti, Publications; Heather Doty, Student Chapter President. Members elected or appointed to the committees are posted on the Society For Biomaterials website at www.biomaterials.org.

Election of Awards, Ceremonies and Nominations

The following members were elected to the 2010-2011 Awards, Ceremonies and Nominations Committee: Jason Burdick, University of Pennsylvania; Monty Reichert, Duke University; John Fisher, University of Maryland; Todd McDevitt, Georgia Institute of Technology.

Election of Membership Committee

The following members were elected to the 2010-2011 Membership Committee: Horst Von Recum, Case Western Reserve University; Mariah Hahn, Texas A&M University; Julie Stenken, University of Arkansas; Stephanie Bryant, University of Colorado.

Bylaws Amendments

The members present approved the proposed changes to the SFB bylaws, which were distributed to all members prior to the meeting. Updated bylaws have been posted on the SFB website. Amendments passed included adding the national Student Chapter president to the SFB Governing Council, making the editors of the Society's publications honorary officers, and revising Article IX on the Special Interest Groups to be less operational.

Committee News

The Society committees are hard at work as always.

Awards Ceremonies and Nominations

Nominations are being sought for Officers and Awards. Please see the Call for Nominations on Pg. 5 for more details. To nominate a colleague or yourself for an award or position on the SFB Board of Directors, please visit the SFB website at www.biomaterials.org.

Devices and Materials

The committee is investigating ways to attract more industry members as well as provide clinical and tutorial relevance in the annual meeting program and throughout the year. The Committee is also investigating the possibility of hosting a webinar.

Education and Professional Development

The new Biomaterials Days program has been a huge success in raising the visibility of the field among students and in acquiring or rejuvenating student chapters. Future Biomaterials Days are planned, and grant applications are being solicited for 2010 and 2011. Please visit the website or contact Dan Lemyre (dlemyre@biomaterials.org) for more details.

Finance

As Tony Mikos reported at the 2010 Annual Business Meeting, the Society's finances are healthy. At the Finance Committee's recommendation, the Board has approved a measure to invest the C. William Hall Scholarship Fund reserves in certificates of deposit, which will allow these funds to accrue their own interest and ensure the availability of scholarships for years to come.

Long-Range Planning

This committee is evaluating and monitoring the implementation of the Society's strategic plan and will use results from membership surveys to help guide future efforts. All survey results are available on the SFB members-only website.

Meetings

The 2011 Annual Meeting will be held in Orlando, Fla., April 13-16, and the Board has approved a plan to hold a small symposium in New Orleans, October 4-6, 2012. The Society staff are also beginning to investigate location options for the 2013 Annual Meeting.

Membership

Membership has increased this year, especially student membership. Biomaterials Days are credited with the increase in student membership. The Committee plans to target four or five universities each year as a way to bring in new chapters and members. In addition, a special outreach program to academic department chairs and industry researchers is underway. More details will follow in the months ahead.

Program

Ideas have been solicited for the 2011 program and were evaluated by the Program Committee during June, with full proposals being invited in July. Abstracts for these proposed sessions will be solicited in September, and the abstract deadline will be in early November.

Publications

The Society has a new book series contract with publisher John Wiley and Sons. The Society now has established groups on Facebook and LinkedIn; all members are invited to join and participate. In addition, a request for proposals for the positions of editors of the *Biomaterials Forum* and the Society's website have been distributed, as the terms for each of those editors expire at the end of this year.

Special Interest Groups

The Society's Special Interest Groups (SIGs) are encouraged to submit articles for the *Biomaterials Forum* and to contribute content to the website. At the moment, four SIGs have created public websites.

IUSBSE/WORLD BIOMATERIALS CONGRESS

The next WBC will be held June 1-5, 2012 in Chengdu, China. A call for proposals will be released in mid-summer 2010. In order to assist with travel logistics and fares, the Society is in the preliminary planning stages of organizing a US delegation for Chengdu.

If you have any questions, require any information, or have suggestions for improved services, please feel free to contact the Society's headquarters office:

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URL: www.biomaterials.org

CALL FOR NOMINATIONS

Society For
Biomaterials

The Society For Biomaterials is soliciting nominations for the 2011 Awards listed below and for the following Board of Directors positions:

- President-Elect
- Secretary-Treasurer-Elect
- Member-At-Large

2011 Awards:

- Founders Award
- C. William Hall Award
- Clemson Award for Applied Research
- Clemson Award for Basic Research
- Clemson Award for Contributions to Literature
- Technology Innovation & Development Award
- Young Investigator Award
- Student Award for Outstanding Research
- Outstanding Research by a Hospital Intern, Resident, or Clinical Fellow Award

Nominations Deadlines

Awards: September 17
Board of Directors: September 24

To nominate someone for an award or position on the SFB Board of Directors, please visit:

www.biomaterials.org

From the President

Continued from page 3

We have a very active student group of members serving as student chapter officers, members of committees, meeting assistants and presenters at our annual meeting. This year the students were instrumental in two major accomplishments: the Social Media Policy and the Biomaterials Days. Thank you: Margaret Phillips, Heather Doty, Kara Spiller, Kristen Moffat, Daniel Alge. A special note of appreciation to the individuals (faculty and students) who helped to organize the Biomaterials Days: Elizabeth Cosgriff-Hernandez, Texas A&M University; David Puleo and Nicholas Ziats, University of Kentucky and Case Western Reserve University; Jiro Nagatomi and Delphine Dean, Clemson University; Helen Lu and Kristen Moffat, Columbia University.

Several advisory committees were formed to assist the Board and Council. I sincerely appreciate your guidance throughout the past year. The Academic Advisory Committee was instrumental in activating the Hall Scholarship. Thank you Joel Bumgardner, Hamed Benghuzzi, and Michelle Tucci. The Clinician Advisory Committee was responsible for organizing the Surgeon's Panel on Overcoming Obstacles to Innovation held during the annual meeting. Thank you Audrey Tsao and Stuart Goodman. A task

force of the Devices and Materials Committee served as an Industry Advisory Board. Thank you Gabriele Niederauer for leading this group.

The productivity of the past year would not have been possible without the support of our management team at Association Headquarters. Thank you Dan Lemyre, Anthony Celenza, Rebecca Riedesel, Astrid Schrier, Gail Valente, Leslie Clark, and BreAnne Clark.

My year as President of the Society For Biomaterials would not have been possible without the support from my colleagues, friends, and, especially, my family. Thank you for making this possible.

Next year promises to bring new challenges and successful programs. Jeremy Gilbert has been a very active and skillful President-Elect. I look forward to where he will lead the Society. I know he will be leading a knowledgeable, dedicated membership.

The Seven Habits of a Successful SFB

Lynne Jones, President

In 1989, Stephen Covey published a book, *The Seven Habits of Highly Successful People*, that has had a significant impact on the business world. I have seen this book have a tremendous impact on the operations of several organizations, and I recommend it highly to others who want to not only be productive but be effective. In reflecting on the past several years as President and as a member of the Board and Council, I would like to offer my suggestions for maintaining a highly successful Society For Biomaterials.

Vision. Any successful society or association needs vision. We are fortunate we have been steered by outstanding leaders in the field. This is reflected by the quality of our annual meeting, our journals, our participation as advisors at the national level, as well as our interaction with our members and our daily operations. However, it is important for our vision to continue to evolve in the ever-changing world of biomaterials. We can have an impact at so many levels, and we should embrace these opportunities as advisors to government and standards agencies, as educators to academia/industry/government, and as innovators and outstanding researchers.

Promoting Excellence in Research. The Society For Biomaterials has an established track record for holding an exceptional annual meeting with something for every type of member. This includes presentations, both oral and poster, of cutting-edge, outstanding research. Over the history of the SFB, we have been at the forefront of new technology, and this continues today. We must remain committed to identifying new areas of research while continuing to chip away at solutions for today's problems. One of the assets of the Society is the diversity of its membership. We need to take advantage of these differences in perspective to offer novel approaches to the issues facing the biomaterials field.

Education. As our membership is so diverse, our educational needs are also varied. Biologists can benefit from instruction relating to the mechanical or chemical properties of materials, materials scientists can benefit from learning about the immune responses to implanted materials, and so on. I believe a better understanding of the entire translational process from patient to product is needed. It is important to understand why there is a need for a biomaterial in the first place, past and current biomaterials efforts, and what the obstacles to long-term success may be.

In a meeting of Department Chairs held in Seattle, the SFB leadership was challenged to help them develop curriculum for teaching biomaterials. We have the resources and expertise to make a significant impact on the education of undergraduate, graduate, and post-graduate students. We should accept this challenge enthusiastically.

Professional Development. Education does not stop with graduation. Some think professional development is limited to self-help programs and acquiring skills related to management. Professional development is this and so much more. It includes learning new technical skills to stay at the forefront of research or being exposed to other scientific disciplines in order to approach existing problems in a new way and to communicate with other scientists. Professional development also consists of learning how others have navigated through the National Institutes of Health and National Science Foundation grant process or how they have negotiated with industry to develop a new product. We need our experienced members to share their experiences and knowledge of the systems with our less experienced members.

Network. The leadership of the Society For Biomaterials recognizes the importance of networking. Networking is one of the reasons that the Special Interest Groups (SIGs) were formed. SIGs should endeavor to create programs to enhance the networking capabilities of the Society. In addition to conducting social events, SIGs should explore opportunities to hold meaningful discussions regarding the opportunities and issues their memberships may face. This year a luncheon was held for the students to meet with some of our established members. What a success! After the lunch dishes had been cleared away, the buzz heard around the room was tremendous. The Society needs to continue this commitment to our students. And don't forget our young investigators. We need to implement a mentoring program as a resource for our students, young investigators, and individuals looking to change career paths.

Teamwork. We need to take advantage of our best resources—our members. We are proud to say that many of our more senior members are the icons of biomaterials and bioengineering. We need to tap their knowledge and seek their guidance. The younger members are technically savvy and have re-energized our field. We need to bridge these two groups with concrete projects.

While the SFB has been fortunate to have a steady core of volunteers to organize and manage the Society, we need to engage more members in its daily operations. The *Forum* and the website have a need for individuals to provide subject matter on issues of importance to our members. Reviewers of abstracts for the annual meeting are needed. We need members to explore different approaches to increasing our revenue stream. Volunteer. You can contact any member of the Board or Council directly (www.biomaterials.org/Council_Contacts.pdf) or contact the Society For Biomaterials headquarters (info@biomaterials.org).

Fun. The Society For Biomaterials has always been known as the Society where individuals can let their hair down, relax, and have fun. Many of us have made long-lasting friendships through the SFB. We also have many a story from Biomaterials Bashes gone by. As they say, you don't know what you are missing until you don't have it. The SFB saw this happen when we did not hold a Biomaterials Bash. The SIG event recognizing the Clemson Awardees has also been an enjoyable opportunity to meet with our fellow members. I cannot overstate the significance of this aspect of our meeting on the continual growth of our Society. In Seattle, I met several students and young investigators at social gatherings. The beginning of new relationships were formed, and I look forward to watching these members as they become active members of our Society.

At the Business Meeting, I noted that the SFB is in good shape. We have a stable financial picture, an increasing number of student members, journals receiving more manuscripts than ever, and a solid core of members. I believe we have positioned ourselves as the lead organization in the field of biomaterials.

CALL FOR EDITORS PROPOSALS

Biomaterials Forum and www.biomaterials.org

The Society For Biomaterials is seeking a website editor and editor for the *Biomaterials Forum* (published quarterly).

Both editors will serve a five-year term. Applicant must be an Active or Retired Senior member of the Society in order to submit a proposal for either position, and must remain a member in good standing for the entire length of their term.

For detailed requirements and proposal submission information, please visit the Society's website: www.biomaterials.org.

The deadline to submit proposals is July 1, 2010.

Community Calendar

**32nd Annual International
Conference of the IEEE Engineering
in Medicine and Biology Society**
Buenos Aires, Argentina
August 31–September 4, 2010
www.embc2010.embs.org/

TERMIS-AP Annual Conference
Sydney, Australia
September 15–17, 2010
www.termis.org/ap2010/

**36th Annual National Society
for Histotechnology Symposium/
Convention**
Seattle, WA
September 24–29, 2010
www.nsh.org

**Biomedical Engineering Society
Annual Meeting 2010**
Austin, TX
October 6–9, 2010
www.bmes.org

**American Institute of Chemical
Engineers Annual Meeting**
Salt Lake City, UT
November 7–12, 2010
www.aiche.org

**2010 Materials Research
Society Meeting**
Boston, MA
November 30–
December 2, 2010
www.mrs.org

**57th Orthopaedic Research Society
Annual Meeting**
Long Beach, California
January 13–16, 2011
www.ors.org

The Society's Chance to Help Shape Biomaterials Education

If you have attended SFB annual meetings, you will know that, among the many science-focused sessions, the conference also hosts sessions devoted more specifically to biomaterials education. Of course, most of us attend annual meetings to learn about the latest advances in biomaterials research and to network with colleagues, but there is also a place at such gatherings for education-focused sessions. Our Society has the opportunity and responsibility to shape how biomaterials science is taught and learned.

Every SFB meeting addresses biomaterials education in some way, but in the paragraphs below I have relayed my experiences in helping organize sessions with a focus on education. I would be happy to hear from other SFB members about similar sessions they have organized or attended.

In 2007 at the SFB Annual Meeting in Chicago, Stephanie Bryant (University of Colorado) and I co-organized a session titled "Developing Best Practices in Tissue Engineering Education." The lead speaker was Prof. Mark Saltzman (Yale University), who is not only a leader in tissue engineering research, but who also has contributed greatly to the educational side of the field, including writing one of the most widely used textbooks on the topic. Dr. Saltzman gave an excellent presentation titled "Teaching Tissue Engineering: One Professor's Experience at Three Institutions." He relayed his experience teaching tissue engineering to students at Johns Hopkins University, Cornell University, and Yale University. His focus was on how to present material that emphasizes connections among concepts from developmental biology, quantitative descriptions of cell behavior, and design of biomaterials.

Education-themed sessions often face the challenge of drawing an audience when the session is competing with high-quality research symposia at the same meeting. For this reason, Stephanie and I included a book raffle in our session, featuring a variety of tissue engineering-related textbooks donated by Elsevier, which

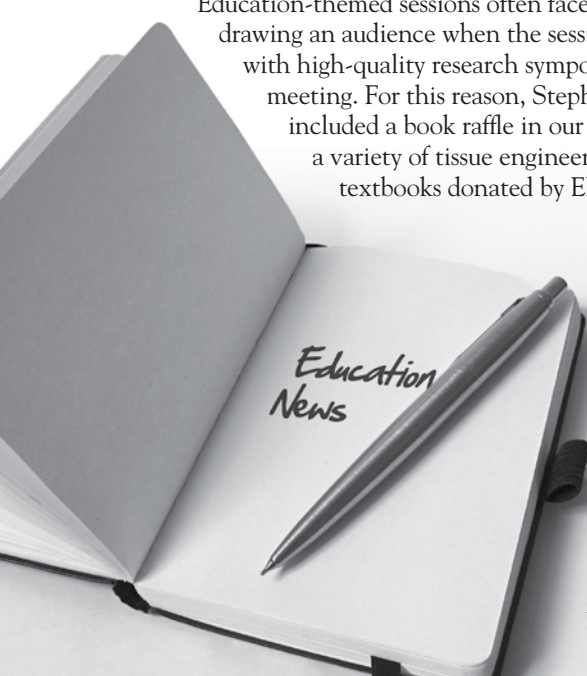
were given away to lucky ticket holders between talks. The grand prize was a copy of *Biomaterials Science: An Introduction to Materials in Medicine* signed by all four of the primary authors: Buddy Ratner, Allan Hoffman, Fred Schoen, and Jack Lemons. The winner was Bret Kelso, a graduate student in Michael Caplan's lab at Arizona State University. And attendance at the session was not a problem, as we filled one of the larger meeting rooms with enthusiastic participants.

The 2009 SFB Annual Meeting in San Antonio, Texas, featured a follow-up tutorial, also called "Developing Best Practices in Tissue Engineering Education." The session began with lead talks from Kristyn Masters (University of Wisconsin) and Tony Mikos (Rice University), who presented their experiences in incorporating biomaterials into tissue engineering courses, as well as their views on the broader knowledge base on which the field is being built. Both talks were first-rate and stimulated discussion with the audience. The presentation slides used by the speakers have been posted in the "Education" area of the Tissue Engineering SIG's web page (www.biomaterials.org/SIGS/Tissue_Engineering/index.cfm). We also repeated the book raffle, though attendance was lighter, which may have had something to do with our time slot: 8:00 am on Saturday (the morning after the bash!) But the attendees got the chance to discuss some of the key issues that arise in teaching tissue engineering. We plan to continue to have sessions on "Developing Best Practices in Tissue Engineering Education" every two years at the SFB annual meeting, and I look forward to a successful session at the 2011 meeting in Orlando, Fla.

I note the 2010 SFB Annual Meeting conference program included at least one session specifically addressing biomaterials education. It was titled "Advancing Biomaterials Education" and consisted of a panel discussion of biomaterials pedagogy and outreach at the college and K-12 levels. I hope you were able to participate in this session and we will hear about its outcomes in a future column. As we go forward, I encourage all SFB members to propose, organize, and participate in education workshops, tutorials and symposia at our annual meetings. Such sessions will help to ensure that biomaterials education evolves as rapidly as the science in our field.

Education Quote of the Quarter:

"Education is not the filling of a pail, but the lighting of a fire." — William Butler Yeats



American Institute for Medical and Biological Engineering News

Government News

Alan Litsky, AIMBE News

Contributing Editor

AIMBE, the American Institute for Medical and Biological Engineering, was founded in 1991 “to establish a clear and comprehensive identity for the field of medical and biological engineering” and “seeks to serve and coordinate a broad constituency of medical and biological scientists and practitioners, scientific and engineering societies, academic departments and industries.” The Society For Biomaterials is a member society of AIMBE, as many AIMBE interests overlap with SFB interests, and two SFB members serve on the AIMBE Council of Societies. More about the organization can be found at the AIMBE website: www.aimbe.org.

The AIMBE staff publishes a bi-weekly Federal Update monitoring governmental activities and initiatives relevant to their constituencies. Several events discussed in recent issues may be of particular interest to SFB members.

Center for Devices and Radiological Health Appoints Director

The U.S. Food and Drug Administration (FDA) has named Jeffrey Shuren, M.D., J.D., as permanent Director of its Medical Devices Division, which reviews products such as implanted heart defibrillators and artificial hips. Shuren had served as acting head of the unit since previous chief Daniel Schultz resigned in August 2009.

Dr. Shuren has held various FDA posts since 1998, including Associate Commissioner for Policy and Planning. In a previous job, he oversaw development of Medicare’s national coverage decisions for medicines and non-implantable devices.

This Medical Device Division has been criticized in recent years for product recalls and controversial approvals. According to documents posted on the FDA website, the unit’s priorities for 2010 will include strengthening product reviews and increasing transparency about decision-making.

FDA Meeting to Improve Device Approval Process

The FDA held a public meeting Feb. 18, 2010, to discuss key challenges related to the premarket notification, or 510(k) process, used to review and clear certain medical devices marketed in the United States. The meeting was designed to permit public discussion of the FDA processes and to solicit suggestions for improvements. It was webcast live. The FDA receives more than 3,000 510(k) submissions each year.

In September, 2009, agency directors announced they had asked the Institute of Medicine (IOM) to conduct a comprehensive study of the process; this study is not expected to conclude until March, 2011. In the meantime, the FDA has convened its own internal working group to evaluate and improve the quality and consistency of the agency’s decision-making in the 510(k) process as well as its administration of the program.

Office of Science and Technology Policy Seeks Inputs from Universities on Commercialization

In September, 2009, President Obama released his national innovation strategy, which is designed to promote sustainable growth and the creation of quality jobs. Two key parts of this strategy are to increase support for the fundamental research at universities and the effective commercialization of promising technologies.

The federal government supports university-based research for a variety of reasons, often transferring viable research discoveries to the marketplace that can pose the greatest challenge to innovators and entrepreneurs. As a result, the administration is interested in working with all stakeholders (including universities, companies, federal research labs, entrepreneurs, investors and non-profits) to identify ways administration can increase the economic impact of federal investment in university R&D and the innovations being fostered in federal and private proof of concept centers. The Office of Science and Technology Policy issued a Request for Information and collected input from the public on ideas for promoting the commercialization of federally funded research.

Health Care Reform includes Medical Research Initiative

The health insurance reform bill signed by President Obama includes a provision to speed the translation and application of promising new treatments for diseases from the laboratory bench to a patient’s bedside. The provision known as the Cures Acceleration Network (CAN) would award grants through the National Institutes of Health to biotech companies, universities and patient advocacy groups to bridge the chasm between a basic scientific discovery and its application as a new health treatment.

CAN grants of up to \$15 million will be used to fund clinical trials and hasten the approvals process. CAN legislation is similar in scope to language being developed and supported by AIMBE and its partners at the National Health Council, which is currently seeking to create an Office of Translational Research in the Office of the Director of the National Institutes of Health. This new program would help not only those conducting basic research, but also those seeking commercialization opportunities for their research.

University and Research Institution News

Institutional News

By Guigen Zhang
Institution News Contributing Editor

The challenge of solving a problem as we yet learn to define it.

In combating diabetes, we bioengineers are busy developing smart glucose sensors with on-board insulin delivery capability with the hope of restoring the normal physiological functionality of the pancreas in an artificial manner. We work along this line of thought because we are bound by the premise that obesity and the build-up of adipose tissue causes cells in the liver, muscle, and fat tissue to become resistant to insulin and that injecting insulin can help cells absorb glucose from the blood to regulate the blood sugar level.

It turns out the problem is not well understood and not yet defined. A new study by Roger Unger and Philipp Scherer questions directly the way we define the problem. They argue the buildup of fatty adipose tissue is actually our body's defense mechanism against not only future famine but also metabolic syndrome—a cadre of symptoms such as obesity and high blood pressure leading to the risk of heart disease, stroke, diabetes and liver disease. They believe lipids, while necessary in small amounts to make cell membranes, are toxic in larger quantities. Absorbing excessive lipids into adipose tissue is our body's way of dealing with such toxicity.

The problem of lipid damage, they argue, is linked to hormones produced not by the pancreas but by adipose

tissue itself. These hormones are leptin and adiponectin. One role of leptin is to oxidize lipids and thus destroy them. Adiponectin, meanwhile, facilitates adipose tissue to absorb lipids. As adipose tissue grows, its production of adiponectin falls, but the production of leptin grows. Excessive leptin, in turn, causes other cells to become resistant to its oxidation effect, thus exposing them to the lipid's toxic effects. In this case, obesity and insulin resistance should be viewed not as a pathologic disease but as an adaptive response—to save themselves when threatened by excessive lipids, cells become insulin resistant, which stops them from taking up extra glucose and turning it into more lipids.

If they are right, injecting insulin to regulate blood sugar level may be counterproductive through inducing more toxic damage to cells due to the heightened level of lipids. This new insight should be a warning for us to redefine the problem and re-think our strategy to solutions. It may point to a new approach to combating diabetes through a leptin paradigm in our bioengineering effort, beyond the conventional insulin paradigm.

This example presents a true challenge for bioengineers in solving a biomedical problem whose nature is yet to be defined. It is certainly not enough to view the problem as predefined and then dive ourselves deep to find solutions. It may be beneficial to view the problem as a moving target as we search for solutions.

Members in the News

Chapter News

Contributed from Press Release

Congratulations to:

Dr. Tony Mikos, Louis Calder Professor of Bioengineering at Rice University, and **Dr. Johnna Temenoff**, Assistant Professor of Biomedical Engineering at the Georgia Institute of Technology, who received the 2010 Meriam/Wiley Distinguished Author Award by the American Society for Engineering Education (ASEE) for their textbook *Biomaterials: The Intersection of Biology and Materials Science*. The ASEE award is offered biannually, with nominated books from professional engineering schools across the U.S. Tony and Johnna's textbook has already been adopted for use by more than 40 U.S. universities.

Dr. Tony Mikos, who is the recipient of the 2010 Food, Pharmaceuticals and Bioengineering Award of the American Institute of Chemical Engineers. The award recognizes an individual's outstanding chemical engineering contribution in the food, pharmaceutical and/or bioengineering industry. These contributions may have been made in industry, government, or academic areas, or with other organizations.

Dr. Lonnie Shea, Professor of Chemical and Biological Engineering at Northwestern University, who was elected to membership in the 2010 class of American Institute for Medical and Biological Engineering Fellows. Founded in 1991, AIMBE is recognized as the leading advocacy group for medical and biological engineering. Lonnie's research focuses on integration of biomaterials and gene/protein delivery to control the local microenvironment and promote the formation of functional tissues.

Dr. Naren Vyavahare, Professor of Bioengineering at Clemson University, who was elected to membership in the 2010 class of American Institute for Medical and Biological Engineering Fellows. Naren's research focuses on treatment of abdominal aortic aneurysms.

Editor's note: Would you like to share some good news about an honor you or a colleague have received? We would love to hear from you; please e-mail news items to kburg@clemson.edu.

Boston Scientific Corp (Boston, Mass.) may sell its pain management unit to shore up capital after a surprise recall and sales suspension of its implantable heart defibrillators last month, industry experts say. Already deeply in debt because of its Guidant Corp acquisition in 2006, Boston Scientific is faced with the loss of an estimated \$5 million in revenue every day. The company has \$2.7 billion in payments due in 2011, after just paying a milestone payment to Abbott Laboratories Inc. tied to the Guidant deal and a payment to the U.S. Department of Justice.

Edwards Lifesciences Corporation (Irvine, Calif.), the global leader in the science of heart valves and hemodynamic monitoring, announced that a federal jury found that Edwards' U.S. Andersen transcatheter heart valve patent is valid and Medtronic CoreValve LLC willfully infringes it. Edwards will move vigorously to enforce this verdict and intends to seek a permanent injunction. The jury also awarded Edwards \$74 million in damages, and the willfulness finding allows Edwards to seek increased damages of up to three times the amount. The patent involved in this suit is part of the Andersen family of patents, which relates to a valve prosthesis for implantation by means of a catheter. Filed in February 2008 in the U.S. District Court for the District of Delaware, this suit was directed at the manufacture or sale of the CoreValve ReValving System in the United States.

Pfizer (New York, N.Y.), the world's largest drug maker, recently paid about \$20 million to 4,500 doctors and other medical professionals for consulting and speaking on its behalf in the last six months of 2009, its first public accounting of payments to the people who decide on drugs to recommend. Pfizer also paid \$15.3 million to 250 academic medical centers and other research groups for clinical trials in the same period. While other pharmaceutical companies have disclosed payments to doctors, Pfizer is the first to disclose payments for the clinical trials. The disclosure does not include payments outside the United States. Pfizer is the fourth major drug company to make such disclosures, following Eli Lilly, Merck and GlaxoSmithKline.

Other News:

The **Food and Drug Administration** (FDA) hopes shuttling its Radiological Devices Branch to the Office of *In Vitro* Diagnostic Device Evaluation and Safety will produce more cohesive policies on diagnostic device review. Issues under the jurisdiction of the radiological branch, which regulates diagnostic imaging equipment as well as other radiation-emitting devices, have been a source of high-profile tensions within the Office of Device Evaluation, but officials in the agency says the move responds to long-term discrepancies between how *in vitro* and *in vivo* diagnostics have been regulated by the FDA.

The **Advanced Medical Technology Association** (AdvaMed) has provided recommendations to FDA on ways to improve the clarity and consistency of the agency's premarket review process for low- and moderate-risk medical devices, also known as "510(k)."

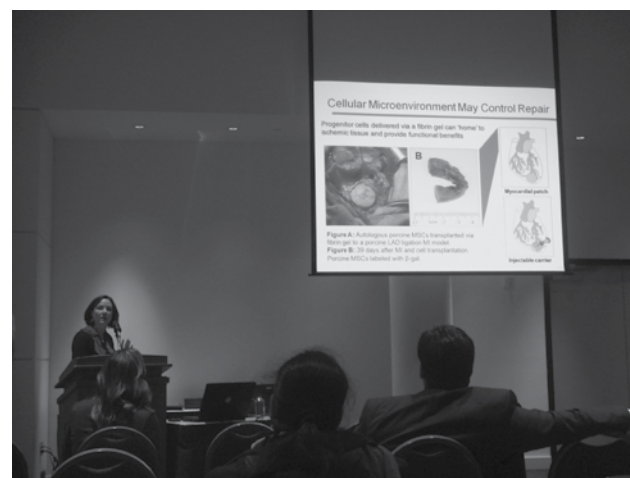
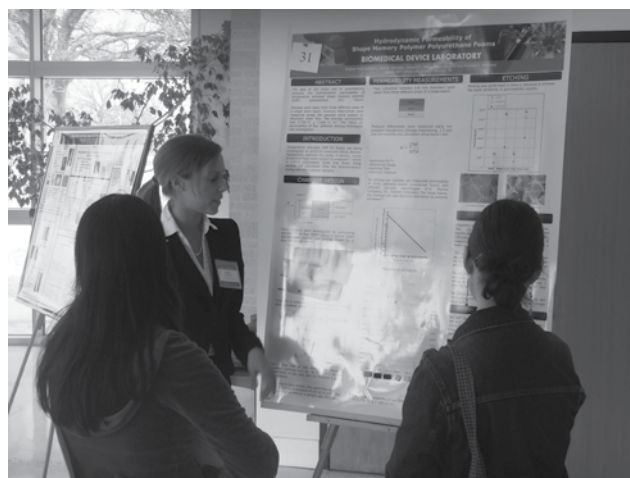
Among its recommendations, AdvaMed proposed that FDA:

- Ensure the content and structure of 510(k) Summaries provided by manufacturers are consistent across all device types. AdvaMed believes FDA should update its guidance about the content of the 510(k) Summary and perhaps include a template for manufacturers to complete.
- Prepare and make publicly available FDA reviewer decision summaries for all 510(k)s, not just for *in vitro* diagnostics as is currently done. The decision summaries would provide interested parties – including FDA reviewers, clinicians and industry – with meaningful information about the subject of the submission and the predicate devices.
- Provide guidance with a template explaining data submission requirements for products eligible for FDA's *de novo* process. This process allows unique, lower-risk products for which there is no predicate to be reviewed via the 510(k) route.

Society For Biomaterials Biomaterials Day at Texas A&M University

Elizabeth Cosgriff-Hernandez
Department of Biomedical Engineering
Texas A&M University

The Biomaterials Day at Texas A&M University (TAMU) was held at the Annenberg Presidential Conference Center in College Station, Texas, February 22, 2010. The goal of the symposium was to enhance networking between academic and industrial sectors and increase student exposure to exciting biomaterials research. The program included a keynote lecture (Tony Mikos, Rice University) and two invited talks by leading biomaterial scientists (Karen Wooley, TAMU and Chuck Griffin, Biostable S&E). Oral presentations from leading institutions (Rice University, TAMU, University of Houston, University of Texas at Austin) and biomedical companies in Texas (KCI, SpineSmith, Zimmer) showcased ongoing research in the region. In total, there were 113 registrants at the Biomaterials Day symposium from 15 universities and four biomedical companies. There was active student involvement in the meeting to address the continued need to encourage student interest in biomaterial careers and foster the development of young scientists. The afternoon poster reception was dedicated to showcasing student research, and poster awards were selected by a panel of judges from regional institutions. This poster session provided valuable experience in presenting research and offered numerous opportunities for students to network with academic and industrial researchers. Forty-eight students participated in the student poster competition, and the following awardees were honored with a plaque and a monetary award of \$100.



Undergraduate Poster Award
Thomas Wilems, TAMU

Graduate Poster Award
Michael Cuchiara, Rice University

Graduate Poster Award
Mary Beth Browning, TAMU

TAMU Steering Committee:

Elizabeth Cosgriff-Hernandez
Biomedical Engineering

Melissa Grunlan
Biomedical Engineering

Michael Pishko
Chemical Engineering

Mariah Hahn
Chemical Engineering



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